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Re: Patent Term Extension
Application for
U.S. Patent No. 4,382,938

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,382,938 issued May 10, 1983, which claims the human drug product Ambien, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be five years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 30, 1993. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (1,296) + 1,417 \\ &= 2,065 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date, the entire period has been considered. No determination of a lack of due diligence was made.

The five year limitation of 35 USC § 156(g)(6)(B) applies in the present situation because the patent was issued before the date of enactment (September 24, 1984) of 35 USC § 156, and no request for an exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act was submitted before such date. Since the period of extension calculated under 35 USC § 156(c) for the patent cannot exceed five years under 35 USC § 156(g)(6)(B), the period of extension will be for five years.

The 14 year exception of 35 USC § 156(c)(3) does not operate to further reduce the period determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,382,938 a certificate of extension, under seal, for a period of five years.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,382,938
Granted:	May 10, 1983
Applicant:	Jean-Pierre Kaplan et al.
Owner of Record:	Synthelabo
Title:	IMIDAZO [1,2-a] PYRIDINE DERIVATIVES AND THEIR APPLICATION AS PHARMACEUTICALS
Classification:	514/393
Product Trade Name:	Ambien
Term Extended:	Five years

C.E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Ambien
FDA Docket No.: 93E - 0087